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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/126,559	07/30/98	CAPON	D 50130-E/JPW/

HM12/0404

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EXAMINER	
BRUMBACK, B	
ART UNIT	**PAPER NUMBER**
1642	14

DATE MAILED: 04/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.	Applicant(s)
09/126,559	Capon et al.
Examiner	**Group Art Unit**
Brenda Brumback	1642

THE PERIOD FOR RESPONSE: [check only a) or b)]

a) ☒ expires *six* months from the mailing date of the final rejection.

b) ☐ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on _____ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on *Mar 19, 2001* has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

☒ The proposed amendment(s):

☒ will be entered upon filing of a Notice of Appeal and an Appeal Brief.

☐ will not be entered because:

☐ they raise new issues that would require further consideration and/or search. (See note below).

☐ they raise the issue of new matter. (See note below).

☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

☐ Applicant's response has overcome the following rejection(s):

☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attached.

☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: _____

Claims objected to: _____

Claims rejected: *1, 4, 8, 37, 40, and 55-58*

☐ The proposed drawing correction filed on _____ ☐has ☐has not been approved by the Examiner.

☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ .

☐ Other

DETAILED ACTION

Attachment to Advisory Action

1. This action is responsive to the amendment after final filed 03/19/2001. Claims 20, 25, 59, 62, 77, 91, 94, and 108-111 were canceled. Claims 1, 4, 8, 37, 40, and 55-58 are pending and under examination.

Claim Rejections - 35 USC § 112

2. The rejection of claims 1, 4, 8, 37, 40, and 55-58 under 35 U.S.C., second paragraph, for indefiniteness of the preamble and for lacking a correlation step is maintained. Applicant's arguments have been fully considered but they are not persuasive for the following reasons.

Applicant argues that the disclosure teaches (page 16, lines 21-26) antiviral drug susceptibility at page 16, lines 21-26 as the concentration of the anti-viral agent at which a given percentage of viral replication is inhibited. While the examiner agrees that the disclosure teaches the meaning of virus or viral susceptibility, applicant's claims are not limited to virus or viral susceptibility; they are drawn to a method for determining susceptibility for an HCV anti-viral drug. Thus, the claims are indefinite because it is unclear if susceptibility is limited to virus susceptibility or if it encompasses some other undefined susceptibility. Applicant may overcome this rejection by amending claims 1 and 37 to recite either viral susceptibility or virus susceptibility, such as "A method for determining virus susceptibility for an HCV anti-viral drug

... " and by amending claims 55-58 something like, "A method for determining virus (or viral) resistance to an HCV anti-viral drug...".

Applicant argues that claim 1 recites a correlation step as step (d) and further argues that it is clear that the comparison of the measurement of the indicator gene in the resistance test vector in the presence and absence of the HCV antiviral drug correlates with a determination of antiretroviral drug susceptibility as recited in the preamble. For clarification of the record, the preamble does not recite antiretroviral drug susceptibility, but rather cites "susceptibility for an HCV anti-viral drug", as has been previously discussed herein; also, the art does not teach that HCV is a retrovirus. While the examiner agrees that it is clear that comparison of the measurement of the indicator gene in the presence and absence of the HCV antiviral drug is the basis for determining viral drug resistance, there is no correlation step in the claims describing how the results of the assay allow for the determination, *i.e.* how are the measurements correlated to drug susceptibility or resistance? Is an increase or decrease in the measured concentration of antiviral drug at which a given percentage of indicator gene expression is inhibited indicative of drug susceptibility or of drug resistance? Absent this correlation, the claims are indefinite.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and

should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB
April 2, 2001

Brenda Brumback,
Patent Examiner